

**REMARKS/ARGUMENTS**

The Examiner's attention to the present application is noted with appreciation.

**Restriction/Election.** Applicant affirms the election of Group I, claims 1-4. Claims 5-32 are cancelled, and claims 33-35 are added. Applicant retains the right to file continuing or divisional applications on the cancelled claims.

**Claim Rejections - 35 U.S.C. § 102.** Applicant respectfully traverses the rejections as set forth below.

Claim 1 is rejected as being anticipated by Szirtes et al. (GB2109796). As noted in the Office Action (page 4), Szirtes et al. discloses only tripeptides having anorexigenic activity of the formula X-Y-Pro-OH. Claim 1 has been amended such that it claims pharmaceutical preparations including a manufactured peptide of the formula pGlu-R<sup>1</sup>-Pro-NH<sub>2</sub>. It is asserted that the terminal amino group -NH<sub>2</sub> renders the peptides patentably distinct over Szirtes et al., which discloses a free acid form of tripeptide with a terminal -OH group.

Claim 1 and 3 are rejected as being anticipated by Sievertsson et al. (J. Med. Chem.). It is noted that Sievertsson et al. determined that there was no hormonal activity with pGlu-Trp-Pro-NH<sub>2</sub>, and thus for the purposes evaluated therein the peptide was inactive. See page 220, first column, second full paragraph, page 220, second column, third full paragraph ("...inactive compounds .... inactivity of pGlu-Tyr-Pro-NH<sub>2</sub>...") and page 221, first column, first full paragraph following Table IV. The Office Action asserts that because the "standard used against the peptide was saline" that "the pharmaceutical carrier taught by reference is saline." Applicant respectfully traverses this assertion. Saline is employed here as a **control** (i.e., an inert reference material), not as a **carrier**. There is no teaching or suggestion that peptide pGlu-Trp-Pro-NH<sub>2</sub> was administered in a pharmaceutical preparation that included saline. The mere fact that a control was employed neither teaches nor suggests that the control might be admixed and administered with an active ingredient, or that the control would constitute a "pharmaceutical carrier." There is no disclosure of saline serving as a carrier. New claim 34 is drawn to the manufactured peptide pGlu-Trp-Pro-NH<sub>2</sub> in combination with "a buffered and isotonic pharmaceutically acceptable carrier." As is

well known, a simple saline solution is not buffered. Support for the amendment is found, inter alia, at page 9, lines 12-21 of the specification. Thus it is asserted that claims 1 and 3 are free of the prior art, in that Sievertsson et al. discloses that the peptide is inactive, and thus there would be no reason or suggestion to combine such peptide with a pharmaceutical carrier to make a pharmaceutical preparation. Additionally, Sievertsson et al. discloses "saline" only as a control, not as a substance admixed with the peptide, and thus does not disclose a combination of the peptide in a saline solution, or disclose any other pharmaceutical carrier. In any event, claim 34 is drawn to a "buffered and isotonic" pharmaceutical carrier, which in no way is disclosed by Sievertsson et al.

Claims 1 and 4 are rejected as anticipated by Kisfaludy et al. (U.S. 4,299,821). The '821 reference teaches a general formula  $\text{Glp-X-Y-NH-A}$ . In this formula, X can be any of 12 different substituents, Y can be 3 different substituents, and A can be almost an indefinite number of substituents, including hydrogen, a  $\text{C}_{1-10}$  alkyl group or a  $\text{C}_{1-3}$  alkyl group with a dimethylamino substituent. It is submitted that in use of a generic chemical formula to arrive at a specific composition, anticipation can only be found if the classes of substituents are sufficiently limited or well delineated. *Ex parte A*, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990). Here the classes are not sufficiently limited or well delineated.

Claims 1 and 2 are rejected as anticipated by Kisfaludy et al. (U.S. 4,386,073). The '073 reference teaches a general formula  $\text{X-Y-W-NH}_2$ . In this formula, X can be any of 7 different substituents, Y can be 3 different substituents, and W can be 9 different substituents. It is submitted that in use of a generic chemical formula to arrive at a specific composition, anticipation can only be found if the classes of substituents are sufficiently limited or well delineated. *Ex parte A*, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990). Here the classes are not sufficiently limited or well delineated. None of the examples specifically teach the peptide pGlu-Leu-Pro-NH<sub>2</sub>.

Claims 1, 2 and 4 are rejected as being anticipated by Szirtes et al. (J. Med. Chem.). It is submitted that Szirtes et al. does not teach a "pharmaceutically acceptable carrier", and more specifically, does not teach a "buffered and isotonic pharmaceutically acceptable carrier" as set forth in new claims 33 and 35. Contrary to the assertion in the Office Action, Applicant submits that no "pharmaceutically acceptable

carrier" is disclosed in the cited reference. Page 744, "Experimental Section", merely states that the "test compounds were administered in doses of 5 to 80 mg/kg intravenously..." There is no disclosure of any formulation. Specifically, there is no disclosure of a buffered and isotonic pharmaceutically acceptable carrier, as set forth in new claims 33 and 35.

In view of the above amendments and remarks, it is respectfully submitted that all grounds of rejection and objection have been avoided and/or traversed. It is believed that the case is now in condition for allowance and same is respectfully requested.

If any issues remain, or if the Examiner believes that prosecution of this application might be expedited by discussion of the issues, the Examiner is cordially invited to telephone the undersigned attorney for Applicant at the telephone number listed below.

Also being filed herewith is a Petition for Extension of Time to February 6, 2004, with the appropriate fee. Authorization is given to charge payment of any additional fees required, or credit any overpayment, to Deposit Acct. 13-4213. A duplicate of this paper is enclosed for accounting purposes.

Respectfully submitted,

By:



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